

# **EXHIBIT R**



**specifications**

**Clinac iX Accelerator** Innovative platform for today, solid foundation for the future



## Specifications

### Introduction

This specification sheet provides information for the Clinac® iX linear accelerators.

### 1.0 Photon Beams

- 1.1 Energy: Up to three photon beams may be selected in accordance with the specifications and combinations listed in Table 1. The base Clinac iX configuration features a single photon energy.

**Table 1: X-ray Beam Performance**

| X-ray Beam Energy Combinations (MV) |  |                                     |  |                   |  |
|-------------------------------------|--|-------------------------------------|--|-------------------|--|
| Beam I                              |  | Optional Beam II<br>(BJR 17/BJR 11) |  | Optional SRS Beam |  |
| 4                                   |  | 10/10                               |  | N.A.              |  |
| 6                                   |  | 10/10                               |  | 6                 |  |
| 6                                   |  | 16/15                               |  | 6                 |  |
| 6                                   |  | 23/18                               |  | 6                 |  |
| 6                                   |  | 25/20                               |  | 6                 |  |
| 8                                   |  | 16/15                               |  | N.A.              |  |
| 8                                   |  | 23/18                               |  | N.A.              |  |

| Nominal<br>Energy (MV)<br>BJR 17 | Nominal<br>Energy (MV)<br>BJR 11 | $D_{max}$<br>(cm) <sup>1</sup> | %Depth<br>Dose at<br>10 cm Depth <sup>1</sup> | Flatness <sup>2</sup> | Symmetry <sup>3</sup> |
|----------------------------------|----------------------------------|--------------------------------|---|-----------------------|-----------------------|
| 4                                | 4                                | 1.20 ± 0.20                    | 63.0 ± 1.0                                    | ±3.0%                 | 2.0%                  |
| SRS6 <sup>4</sup>                | SRS6 <sup>4</sup>                | 1.60 ± 0.15                    | 67.0 ± 1.0                                    | ±3.0%                 | 2.0%                  |
| 6                                | 6                                | 1.60 ± 0.15                    | 67.0 ± 1.0                                    | ±2.5%                 | 2.0%                  |
| 8                                | 8                                | 2.00 ± 0.15                    | 71.0 ± 1.0                                    | ±2.5%                 | 2.0%                  |
| 10                               | 10                               | 2.40 ± 0.15                    | 74.0 ± 1.0                                    | ±2.5%                 | 2.0%                  |
| 16                               | 15                               | 2.90 ± 0.15                    | 77.0 ± 1.0                                    | ±2.5%                 | 2.0%                  |
| 23                               | 18                               | 3.30 ± 0.15                    | 80.0 ± 1.0                                    | ±2.5%                 | 2.0%                  |
| 25                               | 20                               | 3.50 ± 0.15                    | 81.5 ± 1.0                                    | ±2.5%                 | 2.0%                  |

<sup>1</sup> Depth of Ionization applies to 10 x 10 cm<sup>2</sup> field size measured at 100 cm Target-Skin Distance (TSD).

<sup>2</sup> Flatness is defined as the maximum variation from the mean dose delivered within the central 80% Full Width Half Maximum (FWHM) region measured at 100 cm TSD at a depth of 10 cm. The mean is the average of the maximum and minimum points within the central 80% FWHM region. The specification of ±2.5% applies to both the radial and transverse axes of all square field sizes from 20 x 20 cm<sup>2</sup> to 40 x 40 cm<sup>2</sup>, inclusive. A specification of ±3.0% applies to all square field sizes between 10 x 10 cm<sup>2</sup> and 20 x 20 cm<sup>2</sup>, and to 20 MV for all square field sizes larger than 30 x 30 cm<sup>2</sup>. For the SRS 6MV beam, a specification of ±3.0% applies to all square field sizes between 10 x 10 cm<sup>2</sup> and 15 x 15 cm<sup>2</sup>.

<sup>3</sup> Symmetry is defined as the maximum difference between the X-ray dose delivered to any two points which are equidistant and symmetrical about the central axis and

within the central 80% FWHM region measured at 100 cm TSD at a depth of 10 cm. This specification applies to the radial and transverse axes of all square field sizes from 10 x 10 cm<sup>2</sup> to 40 x 40 cm<sup>2</sup>. For the SRS 6 MV beam, this specification applies to the radial and transverse axes of all square field sizes from 10 x 10 cm<sup>2</sup> to 15 x 15 cm<sup>2</sup>.

<sup>4</sup> Beam matching between 6 MV Beam I and the optional SRS 6 MV beam is provided and defined as follows:

<sup>4.1</sup> The depth of  $D_{max}$  along the central axis in a water phantom at 100 cm TSD is within ±1.5 mm of the average of the two beams. The relative dose at 10 cm depth on the central axis in a water phantom at 100 cm TSD is within ±0.5% of the average of the two beams.

<sup>4.2</sup> The dose at any point within the central 80% of the field along the major axes, normalized to the central axis, is within ±1 percentage point of the average of the two beams. This specification applies to beams at 10 cm depth and field dimensions of 10 x 10 cm<sup>2</sup> and above.



- 1.2 Dose Rate: For Beam I and optional Beam II, the dose rate can be selected in fixed steps of 100 MU/min up to a maximum dose rate of 300, 400, or 600 MU/min. For the optional SRS 6 MV Beam, the dose rate is 800 MU/min (1000 MU/min, Trilogy configuration only). The optional SRS high dose rate supports efficient delivery of stereotactic radiosurgery, stereotactic radiotherapy, and intensity-modulated radiation therapy (IMRT). Refer to section 12.0 for further information. An optional low dose rate mode is also available. Refer to section 13.0 for further information.

| Photon Energy (BJR17) | Photon Dose Rate (MU/min)              |
|-----------------------|--|
| 4 MV                  | 50, 100, 150, 200, 250                 |
| 6-25 MV (standard)    | 100, 200, 300                          |
| 6-25 MV (optional)    | 100, 200, 300, 400                     |
| 6-25 MV (optional)    | 100, 200, 300, 400, 500, 600           |
| SRS 6 MV (optional)   | 800 (1000, Trilogy configuration only) |
| 6-25 MV (optional)    | 5, 10, 15, 20, 40, 60, 80              |

An "MU" is defined for these specifications as one centiGray delivered to a tissue-equivalent material at  $D_{max}$  and 100 cm SSD, with a 10 x 10 cm<sup>2</sup> field size.

- 1.3 Maximum Field Intensity at  $D_{max}$ : The intensity at the depth of maximum buildup ( $D_{max}$ ) does not exceed 109% of the central axis intensity anywhere in the measurement plane of any field size.
- 1.4 Leakage: The X-ray absorbed dose does not exceed 0.1% of the absorbed dose at the isocenter measured anywhere in the patient plane outside of the maximum useful beam. The neutron dose equivalent (Sievert) does not exceed 0.2% of the X-ray absorbed dose (Gray) at the isocenter.

The patient plane is defined as a circular plane with a radius of 2 m, centered on and perpendicular to the axis of the beam at isocenter. The X-ray measurements may be averaged over an area not to exceed 100 cm<sup>2</sup>. In all other directions, the X-ray absorbed dose 1 m from the path of the electrons between the electron gun and the target or electron window does not exceed 0.1% of the absorbed dose at isocenter.

- 1.5 Collimator Transmission: The X-ray transmission of the upper and lower movable collimator does not exceed 0.5%.

- 1.6 Spot Size: The electron spot size is less than 3 mm in diameter at the X-ray target.
- 1.7 Penumbra: The distance between the 20% and 80% isodose lines for a 10 x 10 cm<sup>2</sup> field, measured at a depth of 10 cm with a 100 cm TSD along the major axes, measures less than or equal to 9 mm.
- 1.8 Field Size: The field size is continuously variable from 0.5 x 0.5 cm<sup>2</sup> to 40 x 40 cm<sup>2</sup> as measured at 100 cm TSD. Field sizes larger than 35 x 35 cm<sup>2</sup> are limited to a 49.5 cm diagonal (the diameter of the circle defined by the primary collimator at 100 cm TSD). The field size is defined as the distance along the radial and transverse axes between the points of 50% density on an X-ray film taken at 100 cm TSD with minimum buildup. The optional SRS 6 MV beam field size is limited to a maximum of 15 x 15 cm<sup>2</sup>.
- 1.9 Upper and Lower Independent Collimators: Asymmetrical collimation is provided for upper and lower sets of collimators.
- 1.9.1 Independent, asymmetrical Upper Collimator travel range: 30 cm (-10 cm to +20 cm relative to central axis)
- 1.9.2 Independent, asymmetrical Lower Collimator travel range: 22 cm (-2 cm to +20 cm relative to central axis)

## 2.0 Electron Beams

- 2.1 Clinac iX offers a range of electron energy choices. Clinac iX comes with four (4), five (5), or six (6) electron beams that can be selected in accordance with the specifications and combinations listed in Table 2. The specifications apply to a 15 x 15 cm<sup>2</sup> electron applicator and 100 cm TSD.

### 2.2 Dose Rate:

| Electron Dose Rate (MU/min)                   |
|---|
| 100, 200, 300 (standard)                      |
| 100, 200, 300, 400 (optional)                 |
| 100, 200, 300, 400, 500, 600, 1000 (optional) |
| 888 at 1.6 m (optional for 6 MeV and 9 MeV)   |

An optional high electron dose rate is available at 6 MeV and 9 MeV electron energies. Refer to section 8.1 for further information.

2.3 Field Sizes: A set of five electron applicators is provided, with selection from 6 sizes: 6 x 6 cm<sup>2</sup>, 6 x 10 cm<sup>2</sup>, 10 x 10 cm<sup>2</sup>, 15 x 15 cm<sup>2</sup>, 20 x 20 cm<sup>2</sup>, and 25 x 25 cm<sup>2</sup>. Field sizes are defined

at the isocenter plane, 5 cm from the final field-defining aperture. Hardware is provided to facilitate the fabrication of custom final field defining apertures.

**Table 2: Electron Beam Performance**

**Electron Energy Groups**

| 4-Electron Groups (standard) | Nominal Electron Energy (MeV) | 5-Electron Groups (optional) | Nominal Electron Energy (MeV) | 6-Electron Groups (optional) | Nominal Electron Energy (MeV) |
|------------------------------|-------------------------------|------------------------------|-------------------------------|------------------------------|-------------------------------|
| Group I                      | 4, 6, 9, 12                   | Group I                      | 6, 9, 12, 15, 18              | Group I                      | 4, 6, 9, 12, 15, 18           |
| Group II                     | 6, 9, 12, 15                  | Group II                     | 4, 6, 9, 12, 15               | Group II                     | 6, 9, 12, 15, 18, 22          |
| Group III                    | 6, 9, 12, 16                  | Group III                    | 6, 9, 12, 16, 20              | Group III                    | 4, 6, 9, 12, 16, 20           |
|                              |                               | Group IV                     | 4, 6, 9, 12, 16               |                              |                               |

| Nominal Energy | Depth of Ionization <sup>1</sup> |                  |                 |        | Depth of Dose Value     |          | Flatness <sup>3</sup> | Symmetry <sup>4</sup> (MU/min) |
|----------------|----------------------------------|------------------|-----------------|--------|-------------------------|----------|-----------------------|--------------------------------|
|                | 90%                              | 80%              | 50%             | 30%    | 85%/2 (cm) <sup>2</sup> | 80% (cm) |                       |                                |
| 4              | .89<br>±0.1 cm                   | 1.00<br>±0.07 cm | 1.26<br>±0.1 cm | ≤2.00  | 0.61                    | 1.00     | ±7%                   | 2%                             |
| 6              | 1.71<br>±0.1 cm                  | 1.90<br>±0.07 cm | 2.30<br>±0.1 cm | ≤2.60  | 0.93                    | 1.95     | ±4.5%                 | 2%                             |
| 9              | 2.68<br>±0.1 cm                  | 2.95<br>±0.07 cm | 3.50<br>±0.1 cm | ≤3.90  | 1.45                    | 3.00     | ±4.5%                 | 2%                             |
| 12             | 3.77<br>±0.1 cm                  | 4.15<br>±0.07 cm | 4.89<br>±0.1 cm | ≤5.40  | 2.02                    | 4.25     | ±4.5%                 | 2%                             |
| 15             | 4.68<br>±0.1 cm                  | 5.20<br>±0.07 cm | 6.17<br>±0.1 cm | ≤6.80  | 2.57                    | 5.35     | ±4.5%                 | 2%                             |
| 16             | 4.87<br>±0.1 cm                  | 5.45<br>±0.07 cm | 6.49<br>±0.1 cm | ≤7.30  | 2.67                    | 5.60     | ±4.5%                 | 2%                             |
| 18             | 5.31<br>±0.1 cm                  | 6.10<br>±0.07 cm | 7.41<br>±0.1 cm | ≤8.15  | 3.04                    | 6.40     | ±4.5%                 | 2%                             |
| 20             | 5.52<br>±0.1 cm                  | 6.55<br>±0.07 cm | 8.13<br>±0.1 cm | ≤9.30  | 3.26                    | 6.90     | ±4.5%                 | 2%                             |
| 22             | 5.59<br>±0.1 cm                  | 6.80<br>±0.07 cm | 8.64<br>±0.1 cm | ≤10.00 | 3.37                    | 7.20     | ±4.5%                 | 2%                             |

<sup>1</sup> Depth of Ionization values apply to 15 x 15 cm<sup>2</sup> applicator field size. Electron measurements are made at 100 cm TSD and a nominal 5 cm gap between the bottom of the open field aperture and the water surface. Measurements are defined with a 0.1 cm<sup>3</sup> PTW ionization chamber, or equivalent.

<sup>2</sup> D85%/2 is the depth at which flatness and symmetry are specified. Values are defined at 100 cm TSD using a 15 x 15 cm<sup>2</sup> electron applicator field size. No inverse square corrections are assumed.

<sup>3</sup> Flatness is defined as the maximum variation from the mean electron ionization within the central 80% FWHM region. The mean is the average of the maximum and minimum points within the central 80% FWHM region.

This specification applies to square electron applicator field sizes from 10 x 10 cm<sup>2</sup> to 25 x 25 cm<sup>2</sup> measured on the radial and transverse axes. A specification of ±5% is applied to 6 MeV for 10 x 10 cm<sup>2</sup> applicator field size. The diagonal flatness specification for the above applicator field sizes is ±5%, except 4 MeV. The 4 MeV flatness specification applies only to the radial and transverse axes.

<sup>4</sup> Symmetry is defined as the maximum difference between the ionization delivered to any two points that are equidistant and symmetrical about the central axis and within the central 80% FWHM region. This specification applies to the plane normal to the central axis and to square electron applicator field sizes from 10 x 10 cm<sup>2</sup> to 25 x 25 cm<sup>2</sup>, except 4 MeV. The 4 MeV specification applies only to the radial and transverse axes.



- 2.4 X-ray Contamination: For nominal energies up to 10 MeV, the X-ray contamination is less than or equal to 2%. For nominal energies greater than 10 MeV, the X-ray contamination is less than or equal to 5%. This specification is defined in water with a 100 cm TSD, at a depth of 10 cm beyond the depth of the 10% isodose line, with a 15 x 15 cm<sup>2</sup> electron applicator.
- 2.5 Patient Plane Leakage: Electron leakage is less than or equal to 2% of the absorbed dose on central axis. This specification is defined in air, at 100 cm TSD with 1 cm buildup, in an area 4 cm outside the 50% isodose line.
- 2.6 Applicator Side Plane Leakage: The leakage does not exceed 9% of central axis ionization at D<sub>max</sub>. This specification is defined along a plane coincident to the side of the electron applicator, measuring 10 cm up from the bottom of an applicator.

### 3.0 Accelerator System Features

- 3.1 RF Power Source: Varian's high-efficiency klystron is operated in linear amplifier mode and driven by a solid-state oscillator, with power and frequency automatically locked to required operating levels.
- 3.2 Electron Gun: The unique triode design of the electron gun allows exact and safe control of electron beam levels in the accelerator. It provides the ability to rapidly and precisely vary output dose rate and turn the beam on or off. This capability is especially important in dynamic dose delivery, where high-speed beam gating and elimination of dark current during beam-off time periods is important. The gun is demountable, resulting in minimum system downtime during replacement.
- 3.3 Standing Wave Accelerator: The Varian side-coupled cavity accelerator structure has been developed for optimum use of RF power and narrow output spectrum at the design energy for the guide. Spectrum characteristics, with and without use of an energy switch, have been matched to the transport requirements of the downstream bend magnet to ensure high dose rate capability.

- 3.4 Patented Non-Contacting Energy Switch: In each of the X-ray treatment modes where this is utilized, the switch functions to change the ratio of electric fields between two sections of the accelerator guide. This is done in such a way as to ensure a tight energy spectrum over a wide range of photon energies, with consequent high output capability and stable operation.
- 3.5 Solenoid: A full-length magnetic solenoid assures high electron beam transmission through the accelerator structure, resulting in reduced stray-radiation and efficient use of RF power.
- 3.6 Bend Magnet: This patented 270° bend magnet is fully achromatic, with one-to-one imaging for superior transport and control of the beam from the accelerator. The magnet is also equipped with energy slits fixed at ±3%, enabling output beams of consistently high quality and precise dosimetry.
- 3.7 Radial and Transverse Steering Systems: These systems ensure basic beam alignment in all modes, as well as gantry orientation. Ion chamber sensors, in conjunction with the steering coils and servo electronics, maintain beam symmetry changes to within 2% under all conditions.

### 4.0 Dosimetry System

The following specifications apply for both independent dosimetry channels:

- 4.1 Reproducibility with Energy: Precision of the dosimetry measurement system for each energy is ±1% or ±1 MU, whichever is greater, at a fixed dose rate.
- 4.2 Dose Calibration Linearity versus Total Dose: The linearity is as follows:
  - 1% for 20-999 MU
  - 2% for 10-20 MU
  - 3% for 5-10 MU
- 4.3 For photon Beam I and optional Photon Beam II, doses up to 999 MU can be delivered. For the optional SRS 6 MV Beam, doses up to 6,000 MU per field can be delivered. For all electron beams, doses up to 4,000 MU can be delivered.

4.4 Reproducibility of Dose vs. Gantry Angle: The precision of the dosimetry system is  $\pm 1.5\%$  at any gantry angle from 0 to 360 degrees.

4.5 Reproducibility with Dose vs. Dose Rate: The dose rate dependence of the dosimetry system with variations in dose rate from minimum to maximum is less than  $\pm 1\%$  or  $\pm 1$  MU, whichever is greater.

4.6 Beam-Off Interlocks: The radiation beam automatically terminates in the event of any of the following:

- Monitor Units 1 complete
- Monitor Units 2 complete
- Treatment time complete
- Radial symmetry exceeds 2%
- Transverse symmetry exceeds 2%
- Excess dose rate
- Excess dose per pulse
- Excess dose per degree
- Loss of ion chamber bias voltage
- Under dose rate

## 5.0 Beam Matching Specifications

Beam matching of a new high energy Clinac iX accelerator (including the Trilogy configuration) to existing high-energy Clinac iX accelerators, Trilogy configurations of the Clinac iX accelerator, and low- and high-energy Clinac EX accelerators that meet the serial number requirements shown below is available as a purchasable option. If purchased, this option includes on-site demonstration of the matched beams as described below.

Basic or Fine Beam Matching to existing accelerator systems installed outside a 1-year time frame may be available as a purchasable option (refer to section 5.3).

### 5.1 Restrictions and Definitions

- 5.1.1 All specifications apply to fields measured in water with the surface 100 cm from the target of the accelerator system.
- 5.1.2  $D_{max}$  is the depth at which the maximum dose occurs along the central axis of the beam for a  $10 \times 10$  cm<sup>2</sup> X-ray field.
- 5.1.3 R85/2 is one-half the depth where 85% relative ionization occurs on the central axis of an electron field using the  $15 \times 15$  cm<sup>2</sup> applicator.

5.1.4 Major axes lines orthogonal to the central axis of the beam and perpendicular to the sides of rectangular fields.

5.1.5 The term "average" is defined as the average value for the referenced performance specification, calculated using measurements obtained from the new high energy Clinac iX accelerator and the existing accelerator systems(s) to which it is matched.

### 5.2 On-Site Demonstration of Matched Beams

#### 5.2.1 Basic Photon Beam Matching, per beam

5.2.1.1 Basic Matching of Photon X-Ray Beam Energy: For each X-ray beam of the same nominal energy, the depth of  $D_{max}$  along the central axis in a water phantom at 100 cm TSD is within  $\pm 1.5$  mm of the average. For each X-ray beam of the same nominal energy, the relative dose at 10 cm depth on the central axis in a water phantom at 100 cm TSD (normalized to the dose at  $D_{max}$ ) is within  $\pm 1.0\%$  of the average.

5.2.1.2 Basic Matching of Photon X-Ray Beam Flatness: For X-ray beams of the same nominal energy, the maximum dose in the plane normal to the beam axis at a depth of  $D_{max}$  in water at 100 cm TSD is within  $\pm 1\%$  of the average. For each beam of the same nominal energy, the dose at any point within the central 80% of the in-plane and cross-plane axes, normalized to the central axis, measured at a depth of 10 cm in water at a TSD of 100 cm is within  $\pm 2\%$  of the average for the measured values at that point. This specification applies to X-rays at 10 cm depth and field dimensions greater than  $10 \times 10$  cm<sup>2</sup>.



- 5.2.2 Basic Electron Beam Matching, per beam
- 5.2.2.1 Basic Matching of Electron Beam Energy: For each electron beam of the same nominal energy, the relative ionization at 100 cm TSD, the depth of 90%, 80%, and 50%, is within  $\pm 1.0$  mm of the average. This specification applies to the 15 x 15 cm<sup>2</sup> applicator.
- 5.2.2.2 Basic Matching of Electron Beam Flatness: Basic matching of electron beams does not include flatness.
- 5.2.3 Fine Photon Beam Matching, per beam
- 5.2.3.1 Fine Matching of Photon X-Ray Beam Energy: For each X-ray beam of the same nominal energy, the depth of  $D_{\max}$  along the central axis in water phantom at 100 cm TSD is within  $\pm 1.5$  mm of the average. For each X-ray beam of the same nominal energy, the relative dose at 10 cm depth on the central axis in a water phantom at 100 cm TSD (normalized to the dose at  $D_{\max}$ ) is within  $\pm 0.5\%$  of the average.
- 5.2.3.2 Fine Matching of Photon X-Ray Beam Flatness: For X-ray beams of the same nominal energy, the maximum dose in the plane normal to the beam axis at a depth of  $D_{\max}$  in water at 100 cm TSD is within  $\pm 1\%$  of the average. For each beam of the same nominal energy, the dose at any point within the central 80% of the in-plane and cross-plane axes, normalized to the central axis, measured at a depth of 10 cm in water at a TSD of 100 cm is within  $\pm 2\%$  of the average. This specification applies to
- X-rays at 10 cm depth and field dimensions greater than 10 x 10 cm<sup>2</sup>.
- 5.2.4 Fine Electron Beam Matching, per beam
- 5.2.4.1 Fine Matching of Electron Beam Energy: For each electron beam of the same nominal energy, the relative ionization values of 90%, 80%, and 50% at 100 cm TSD, are within  $\pm 1.0$  mm of the average. This specification applies to the 15 x 15 cm<sup>2</sup> applicator.
- 5.2.4.2 Fine Matching of Electron Beam Flatness: For each beam of the same nominal energy, the ionization at any point within the central 80% of the in-plane and cross-plane scans, normalized to the central axis, measured at the depth of  $D_{\max}$  in water at a TSD of 100 cm is within  $\pm 2\%$  of the average of the measured values at that point. This specification applies to the 25 x 25 cm<sup>2</sup> and 10 x 10 cm<sup>2</sup> applicators.
- 5.3 Beam Matching to Accelerator Systems Installed Outside a 1-Year Time Frame
- 5.3.1 Basic or Fine Beam Matching, including on-site demonstration, of a new high energy Clinac iX accelerator to existing accelerator systems installed outside a 1-year time frame is available as a purchasable option for accelerator systems that meet the following requirements:
- Clinac iX, all serial numbers
  - Trilogy configuration, all serial numbers
  - Low-energy Clinacs, serial number 244 and higher
  - Clinac 21 series, serial number 865 and higher
  - Clinac 23 series, serial number 144 and higher
  - Silhouette edition Clinacs, all serial numbers



- 5.3.2 Basic or Fine Beam Matching, including on-site demonstration, of a new high energy Clinac iX accelerator to existing accelerator systems that do not meet the serial number requirements above may be available as a purchasable option.

## 6.o Mechanical Features

### 6.1 Gantry

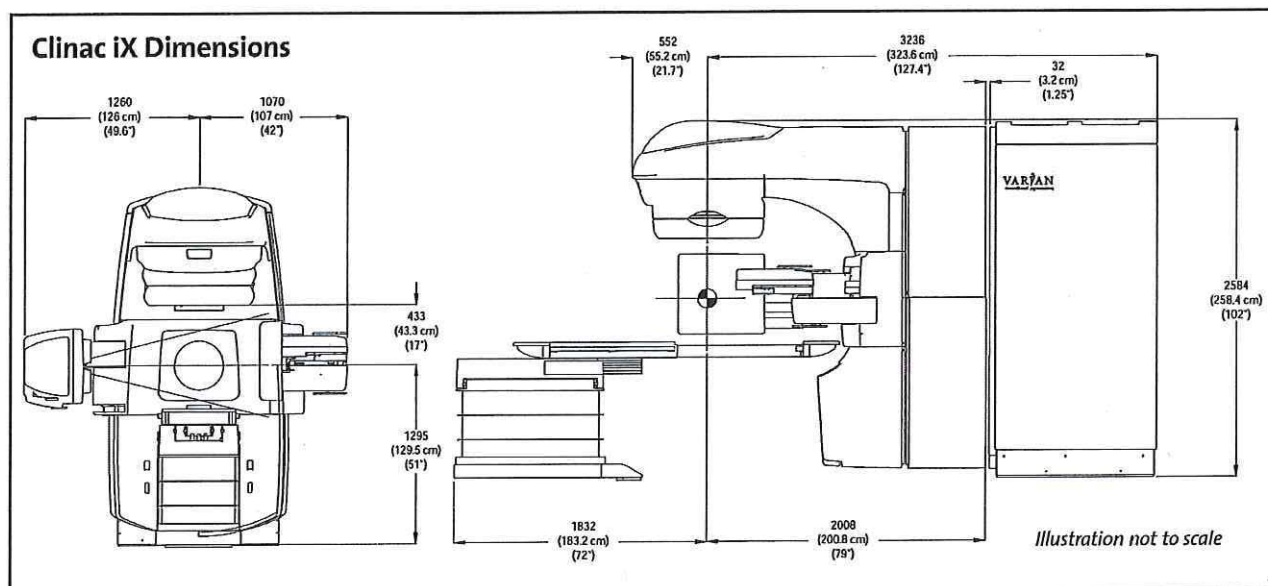
- 6.1.1 Rotation Range:  $\pm 185^\circ$  from the vertical
- 6.1.2 Target to Axis Distance:  $100 \pm 0.2$  cm
- 6.1.3 Mechanical and radiation isocenter accuracy - Standard Beam Isocenter Accuracy
- 6.1.3.1  $\leq 1$  mm radius sphere for gantry and collimator axes without Retractable Beam Stopper
- 6.1.3.2  $\leq 1$  mm radius sphere for gantry, collimator, and couch axes without Retractable Beam Stopper
- 6.1.3.3  $\leq 2$  mm radius sphere for gantry and collimator axes with Retractable Beam Stopper
- 6.1.3.4  $\leq 2$  mm radius sphere for gantry, collimator, and couch axes with Retractable Beam Stopper

- 6.1.4 Mechanical and radiation isocenter accuracy - Optional Fine Beam Isocenter Accuracy

- 6.1.4.1 Not available with Retractable Beam Stopper
- 6.1.4.2 Requires 52-inch Exact® Couch base frame
- 6.1.4.3  $\leq 0.5$  mm radius sphere for gantry and collimator axes
- 6.1.4.4  $\leq 0.75$  mm radius sphere for gantry, collimator, and couch axes

### 6.1.5 Position Indicators

- 6.1.5.1 Scale Conventions
- 6.1.5.1.1 IEC Scale convention per IEC Publication 601-2-1, 1981
- 6.1.5.1.2 IEC 1217 Scale convention per IEC Publication 60601-2-1, 2nd Edition, 1998
- 6.1.5.1.3 Varian Scale
- 6.1.5.2 Digital Readouts:
- Accuracy:  $\pm 0.5^\circ$
  - Resolution:  $0.1^\circ$



- 6.1.5.3 Mechanical Scales:
  - Accuracy:  $\pm 1.0^\circ$
  - Resolution:  $1.0^\circ$
- 6.1.5.4 Gantry Display Only: Optional Enhanced Dynamic Wedge™ (EDW) beam modulation graphic indicator shows that EDW is enabled in either Y1 or Y2 direction.
- 6.1.6 Target to Surface Distance Indicators
  - 6.1.6.1 Optical Distance Indicator:
    - Accuracy:  $\pm 0.1$  cm at 100 cm  $\pm 0.5$  cm at 70 cm and 156 cm
    - Resolution: 0.5 cm
  - 6.1.6.2 Mechanical Front Pointer:
    - Range: 70-110 cm
    - Accuracy:  $\pm 0.1$  cm at 100 cm
    - Resolution: 0.2 cm
- 6.1.7 Isocenter Height (nominal): 129.5 cm
- 6.2 Collimator
  - 6.2.1 Extended Rotation Range:  $\pm 165^\circ$
  - 6.2.2 Position Indicators (gantry and console)
    - 6.2.2.1 Digital Readouts:
      - Accuracy:  $\pm 0.5^\circ$
      - Resolution:  $0.1^\circ$
    - 6.2.2.2 Mechanical Scales:
      - Accuracy:  $\pm 1.0^\circ$
      - Resolution:  $1.0^\circ$
- 6.3 Field Size Collimation
  - 6.3.1 Range: The field size is continuously variable from  $0.5 \times 0.5$  cm<sup>2</sup> to  $40 \times 40$  cm<sup>2</sup> as measured at 100 cm TSD. Field sizes larger than  $35 \times 35$  cm<sup>2</sup> are limited to a 49.5 cm diagonal (the diameter of the circle defined by the primary collimator at 100 cm TSD). The field size is defined as the distance along the radial and transverse axes between the points of 50% density on an X-ray film taken at 100 cm TSD with minimum buildup. The optional SRS 6 MV beam field size is limited to a maximum of  $15 \times 15$  cm<sup>2</sup>.
- 6.3.2 Position Indicators
  - Accuracy:  $\pm 0.2$  cm
  - Resolution: 0.1 cm
- 6.3.3 Light and X-ray Field Coincidence: The field-defining light coincides to within 1.5 mm of the 50% isodensity line on an X-ray film. This is defined at 100 cm TSD with minimum buildup for any field size.
- 6.4 Exact Couch with Indexed Immobilization® patient positioning
  - 6.4.1 The Exact Couch is standard with Clinac iX accelerators. (Specifications and standard vs. optional accessories for the Exact Couch are provided on specification sheet RAD 1951A.)
  - 6.4.2 Motion Controls
    - Two Hand Pendants that control both Clinac iX and Exact Couch
    - Two Couch Side Panels
    - Optional Remote Couch Control
  - 6.4.3 Position Indicators
    - 6.4.3.1 Translation
      - Accuracy:  $\pm 0.1$  cm
      - Resolution: 0.1 cm
    - 6.4.3.2 Rotation
      - Accuracy:  $\pm 0.5^\circ$
      - Resolution:  $0.1^\circ$
- 6.5 Compact stand assembly
  - 6.5.1 Single access and through-door viewing of all gas and water system status indicators
  - 6.5.2 Optional imager electronics (PortalVision™ MV imaging system and On-Board Imager® kV imaging system) incorporated in reduced height stand

## 7.0 Accessories

The following accessories are included as standard with Clinac iX and the Exact Couch:

### 7.1 Collimator Accessories:

- Interface Mount
- Accessory Mount
- Port Film Graticule
- 4-Way Wedge Set (four wedges 15°, 30°, 45°, 60°)
- Five Electron Applicators: A set of five electron applicators is provided, with selection from 6 sizes: 6 x 6 cm<sup>2</sup>, 6 x 10 cm<sup>2</sup>, 10 x 10 cm<sup>2</sup>, 15 x 15 cm<sup>2</sup>, 20 x 20 cm<sup>2</sup>, and 25 x 25 cm<sup>2</sup>.
- Custom Aperture Fabrication Hardware
- Mechanical Front Pointer (holder and 4 rods)
- Drilled Star or solid block trays (Qty 10 - 0.635 cm thickness)

### 7.2 Accessory Spare Parts Kit

## 8.0 Optional Treatment Procedures

8.1 Optional High Dose Total Skin Electron Mode: The Clinac iX accelerator is capable of delivering electron treatments at high dose rates for the purpose of total body skin irradiation with electrons. The dose rate at 1.6 m is 888 MU/min, corresponding to nominally 2,500 MU at isocenter. This mode is available in 6 MeV or 9 MeV.

- 8.1.1 X-ray contamination at calibration point is <1%.
- 8.1.2 Symmetry at isocenter is  $\pm 2\%$ .
- 8.1.3 Integrated dose monitor: 1 to 9,000 MU.
- 8.1.4 Exposure time: 0.1 to 99.9 min.

8.2 Optional Total Body Electron Mode: Delivers 9,000 MU at isocenter with all normal machine safety and dosimetry interlocks operational, and delivers standard energies at standard dose rate ranges.

8.2.1 Special TBE accessory tray is provided.

8.2.2 All beams are calibrated at machine isocenter.

8.2.3 Integrated dose: 1 to 9,000 MU.

8.2.4 Exposure time: 0.1 to 99.9 min.

8.3 Optional Total Body Photon X-ray Mode: Delivers 9,000 MU at isocenter with all normal machine safety and dosimetry interlocks operational, and delivers standard energies at standard dose rate ranges.

Special TBI accessory tray is provided.

8.3.1 All beams are calibrated at machine isocenter.

8.3.2 Integrated dose: 1 to 9,000 MU.

8.3.3 Exposure time: 0.1 to 99.9 min.

## 9.0 Optional Auto Field Sequencing

Auto Field Sequencing (AFS), for use with the 4D Integrated Treatment Console (refer to 4D Integrated Treatment Console Product Brief, RAD 2768A for information and specifications), is optional with the Clinac iX accelerator, and provides automated delivery of multiple coplanar and non-coplanar fields. With this time saving feature, Clinac iX automatically acquires the mode up signal and machine setup information from the 4D Integrated Treatment Console, and then allows the operator to remotely move the gantry, jaws, collimator, and Exact Couch axes (with purchase of optional Remote Couch Motion capability) between coplanar and non-coplanar treatment fields. This feature eliminates the need to go back into the treatment room to alter the machine setup between treatment fields. AFS works in concert with the Millennium™ MLC to deliver both static and dynamic plans efficiently and smoothly. (Refer to Auto Field Sequencing, RAD 6045.)



## 10.0 Optional Dynamic Treatment Procedures

- 10.1 Standard Photon Arc Mode and optional Electron Arc Mode: The Clinac iX accelerator is capable of delivering the following dose over a preset gantry rotation of up to 360 degrees or any fraction thereof. MU per degree (MU/DG) is automatically computed based on the preset total dose and the preset arc segment.

|                           |                             |
|---------------------------|-----------------------------|
| Photon Beam I             | 0.30 MU to 20 MU per degree |
| Photon Beam II (optional) | 0.30 MU to 20 MU per degree |
| SRS 6 MV Beam (optional)  | 0.30 MU to 60 MU per degree |
| All electron beams        | 0.30 MU to 20 MU per degree |

- 10.1.1 Precision: During Arc treatment, the position of the gantry deviates no more than 0.5 degrees from the desired instantaneous gantry angle, and the dose deviates no more than 0.20 MU from the desired instantaneous total dose, as specified by the user-preset total dose and arc segment.

If these tolerances are exceeded, the dose delivery is suspended and the gantry position is targeted to the position dictated by the actual dose delivered. When the gantry is again within 0.5 degrees of the desired position, the treatment will resume. The Dose Position Interlock (DPSN) is asserted if the gantry is not positioned within 0.5 cm of the desired position within 3 seconds.

The DPSN will terminate the beam immediately if the position deviates 3.0 degrees or more from the desired position, or the dose delivered exceeds 0.45 MU for dose rates less than 600 MU/min (0.54 MU for dose rate 600 MU/min and 0.72 MU for dose rates greater than 600 MU/min, applies to version 7.8 and above).

- 10.1.2 Arc Dose Rate: The dose rate during a dynamic arc treatment is automatically modulated between zero and the ceiling dose rate selected in Physics Mode.
- 10.1.3 Arc Direction: The Clinac iX may be programmed to perform arc therapy in either a clockwise or counterclockwise direction.

- 10.2 Optional Enhanced Dynamic Wedge (EDW) Mode: Optional EDW can be used with either Beam I or optional Beam II. EDW utilizes Y-jaws to create wedge shaped dose distributions. Enhanced Dynamic Wedges of 10, 15, 20, 25, 30, 45, and 60 degrees are included, with up to 30 cm (wedge direction) by 40 cm field sizes. (Refer to Enhanced Dynamic Wedge Specification, RAD 1880C.)

## 11.0 Optional Dynamic MLC Techniques

Intensity-modulated radiation therapy (IMRT) and conformal arc therapy are optional advanced dynamic procedures in which the leaves of the optional Millennium MLC move during treatment. Refer to MLC Dynamic Control Specification, RAD 5610B for additional information and specifications.

- 11.1 Arc Dynamic MLC allows delivery of MLC fields as a function of gantry arc angle, also known as conformal arc therapy. An MLC shape change every 2° is supported.
- 11.2 Dose Dynamic MLC allows delivery of MLC fields as a function of percent dose delivered, also known as IMRT. Both dynamic IMRT (i.e., sliding window) and segmental IMRT (i.e., step-and-shoot) techniques are supported. Combinations of the two IMRT techniques also are supported. In addition, Dose Dynamic MLC enables treatment delivery with electronic compensation, in which MLC leaf motion simulates the dosimetric effect of a physical compensator.

**12.0 Optional Stereotactic Mode**

The Clinac iX accelerator is capable of delivering stereotactic treatments at high dose rates and with remote couch motion. This mode is available with purchase of the optional SRS 6 MV photon beam. Both cone- and MLC-based treatment delivery is supported. Beam flatness, symmetry, and other specifications can be found in Table 1.

12.1 Dose Rate: 800 MU per min at  $D_{max}$   
(1000 MU/min at  $D_{max}$ , Trilogy configuration only)

12.2 Maximum dose per field: 6,000 MU

12.3 Maximum field size: 15 x 15 cm<sup>2</sup>

12.4 Maximum dose per degree for arc treatments: 60 MU per degree

12.5 Stereotactic Motion Disable

12.5.1 Mechanical couch locks

12.5.2 Electrical disable for gantry and couch

**13.0 Optional Low Dose Rate (LDR)**

The Low Dose Rate option allows dose rate selection of 5, 10, 15, 20, 40, 60, 80 MU per min in addition to the standard dose rate set of 100-600 MU per min. The option is available for Beam I and optional Beam II.

Reproducibility vs. Dose Rate

- $\leq 10$  MU/min:  $\pm 10\%$
- 15-20 MU/min:  $\pm 5\%$
- $\geq 40$  MU/min:  $\pm 2\%$

Reproducibility vs. MU

- $\leq 10$  MU:  $\pm 3\%$
- 15-20 MU:  $\pm 2\%$
- $\geq 20$  MU:  $\pm 1\%$

**14.0 Treatment Command Center**

Ergonomic command center configuration places all control modules, monitors, and user interaction devices within easy reach of the operator. Direct access application selection simplifies the workspace by reducing the number of input devices (e.g., keyboard and mouse), while allowing continuous viewing of all applications.

**15.0 In-Room Display**

A high-resolution, flat screen, color display monitor is included for in-room display of Clinac iX accelerator parameters and patient-specific information.

**16.0 Typical Facility Requirements****16.1 Electrical Requirements**

16.1.1 Typical 60Hz: 200-240 VAC, line-to-line, 3-phase, 4-wire plus ground, 45 KVA load.

16.1.2 Typical 50Hz: 360-440 VAC, line-to-line, 3-phase, 4-wire plus ground, 45 KVA load.

16.2 Cooling Water Requirements: The cooling water requirements can be satisfied with a one-pass system (domestic supply and waste return) or a closed loop system.

16.3 Ventilation must be sufficient to remove 8 kW from treatment room and 1 kW from control console.

16.4 Compressed Air Requirements: Instrument quality air is required.

16.5 Machine installation does not include rigging, grouting the baseframe into the floor, conduit runs, attaching utilities to the machine, or construction of therapy room.

16.6 For facilities requirements refer to the Clinac iX Installation Data Package.

**16.7 Optional On-Board Imager Power Requirements**

16.7.1 Input voltage: 400 to 480 Vac ( $\pm 10\%$ ), 3-phase, 4-wire plus ground

16.7.2 Input frequency: 50 or 60 Hz ( $\pm 1\%$ )

For comprehensive facilities requirements refer to the On-Board Imager Installation Data Package.



## Additional Option Descriptions

### 4D Integrated Treatment Console

The 4D Integrated Treatment Console provides a streamlined front end to the Clinac iX delivery system. The console integrates use of the Clinac iX accelerator, Millennium MLC, and MV imager into one application on a single workstation. For image-guided radiotherapy using kV images, the console is used in combination with the On-Board Imager workstation. The 4D Integrated Treatment Console uses a DICOM RT interface to communicate with the VARiS Vision™ oncology information system and other information system databases.

### Millennium 52-Leaf Multileaf Collimator

The Millennium 52-leaf MLC offers 1.0 cm leaf resolution at isocenter for a 26 cm x 40 cm field. The Millennium MLC operates in static, dynamic, and conformal arc modes. The static mode provides efficient beam shaping for 3D conformal radiation therapy. The dynamic mode enables IMRT with both step-and-shoot and sliding window delivery. The conformal arc mode enables conformal arc therapy in which the leaves always conform to the outer boundary of the target as the gantry rotates around the patient.

Refer to MLC RAD 5609 for additional MLC information and specifications.

### Millennium 80-Leaf Multileaf Collimator

The Millennium 80-leaf MLC offers 1.0 cm leaf resolution at isocenter for a 40 cm x 40 cm field. The Millennium MLC operates in static, dynamic, and conformal arc modes. The static mode provides efficient beam shaping for 3D conformal radiation therapy. The dynamic mode enables IMRT with both step-and-shoot and sliding window delivery. The conformal arc mode enables conformal arc therapy in which the leaves always conform to the outer boundary of the target as the gantry rotates around the patient.

Refer to MLC RAD 5609 for additional MLC information and specifications.

### Millennium 120-Leaf Multileaf Collimator

The Millennium 120-leaf MLC offers 0.5 cm leaf resolution at isocenter for the central 20 cm of the 40 cm x 40 cm field. The Millennium MLC operates in static, dynamic, and conformal arc modes. The static mode provides efficient beam shaping for 3D conformal radiation therapy. The dynamic mode enables IMRT with both step-and-shoot and sliding window delivery. The conformal arc mode enables conformal arc therapy in which the leaves always conform to the outer boundary of the target as the gantry rotates around the patient.

Refer to MLC RAD 5609 for additional MLC information and specifications.

### Stereotactic Components

Choose either the Varian or BrainLAB package of stereotactic components. Each package includes:

- Conical collimators for circular arc treatments and collimator mount
- Stereotactic headring and couch mount
- Frameless stereotactic intracranial immobilization
- Stereotactic treatment planning capability for cones and the Millennium 120-leaf MLC
- Optical positioning system (available only with the Varian package)

### Fine Beam Accuracy

Provides enhanced isocenter accuracy for gantry, collimator, and couch axes (refer to section 6.1.4).

### Collimator Accessories

- Electron Arc Applicators and Mold Frames
- Additional Block Tray sets
  - Solid or Slotted
  - 0.635 cm or 1 cm thickness
- Compensator Mount
- Upper and Lower Compensator Trays
- Extended Spare Parts Kit



### Custom Coding

Custom Coding provides Clinac iX system recognition of the presence of one or more beam-shaping accessories. Accessory recognition includes confirmation of the presence of a beam-shaping accessory in one of four possible accessory positions and identification of the type of accessory. Standard Varian beam-shaping accessories (e.g., 30-degree wedges) are identified by name. Custom beam-shaping accessories (e.g., blocks in Varian-provided block trays or custom final field defining apertures for electron applicator systems) are identified by a custom code for that accessory.

### PortalVision™ aS500 MV Imager

The PortalVision aS500 is an MV imaging system that allows for verification of patient setups and treatment portals.

The amorphous silicon detector has an active imaging area of 40 cm x 30 cm with a pixel resolution of 512 x 384. Image acquisition is supported before, during, and after treatment.

Match and Review software is included for image analysis.

A motorized, retractable arm is used to position and hold the detector.

Refer to PortalVision aS500 Specification, RAD 2252D for information and specifications.

### PortalVision™ aS1000 MV Imager

The PortalVision aS1000 is an MV imaging system that allows for verification of patient setups, treatment portals, and pre-treatment QA.

The amorphous silicon detector has an active imaging area of 40 cm x 30 cm with a pixel resolution of 1024 x 768. Image acquisition is supported before, during, and after treatment.

Match and Review software is included for image analysis.

A motorized, retractable arm is used to position and hold the detector.

Refer to PortalVision aS1000 Specification, RAD 2553A, for information and specifications.

### On-Board Imager Patient Positioning and Target Localization System

The On-Board Imager provides high-quality kV images in the treatment room for target localization, patient positioning, and motion management. Refer to On-Board Imager Specification, RAD 9502G, for information and specifications. The following clinical capabilities are supported:

- Online setup correction based on either a kV-kV or kV-MV pair of radiographs
- Automated and manual alignment of a pair of radiographs to their reference images
- Acquisition of gated radiographs
- Online setup correction based on radiopaque markers
- Pretreatment verification of gated treatment portals using kV fluoroscopy
- Remote couch motion to correct patient setups
- Optional: Acquisition of Cone-beam CT scans

### Remote Couch Motion

Control of couch motion at the treatment console for

- Corrective motions: small translations (in x, y, and z) and small rotation of the couch to fine-tune patient setups
- Planned motions: large rotations of the couch to sequence between non-coplanar fields and arcs

### Real-time Position Management™ (RPM) System

The RPM system enables passive, real-time monitoring of patient respiration for the purpose of intrafraction motion management. Two gating systems are provided. Each system includes an infrared tracking camera, external marker block, and RPM system workstation. The RPM system supports gated treatment delivery and image acquisition on Clinac iX accelerators, gated simulation on compatible simulators (not all simulators are supported), and gated CT acquisition on compatible third-party CT scanners (not all CT scanners are compatible). Depending on the capabilities of the CT scanner, the RPM system supports both retrospective and prospective gating of CT scans. Refer to Real-time Position Management Specification, RAD 5616A for additional information.

**LaserGuard™ Collision Detection System**

LaserGuard monitors the MLC collimator face with a plane of infrared light that emanates from a device located within the gantry. Any object that intrudes into this area, called the protection zone, triggers an emergency stop of all accelerator motion. Refer to Auto Field Sequencing with LaserGuard Specification, RAD 6046 for information and specifications.

**Argus™ QA Software**

Argus provides powerful software tools for automation of quality assurance data acquisition, data analysis, visual display of data, and reporting. Argus also provides a centralized database for digital storage of data.

The Argus QA software provides quality assurance modules for linear accelerators, including static and dynamic MLC using DynaLog™ file analysis, CT simulators, standard simulators, film processors, and HDR brachytherapy systems.

**Portal Dosimetry**

Portal Dosimetry enables use of the MV imager to record the intensity patterns of IMRT fields for pretreatment quality assurance of IMRT planning and delivery.

Portal Dosimetry includes integrated image acquisition mode for recording of IMRT fields and image viewing and analysis software. (\*Use of the image analysis software is optimized when the reference dose image is calculated as dose to amorphous silicon. Currently, only the Eclipse™ treatment planning system offers this capability.)

**Clinac iX Treatment Console Area Packaging**

Compact packaging and cable management of Varian-provided workstations, control modules, and other ancillary devices for easy site preparation and enhanced treatment console area space management. A variety of packaging configurations are available for optimal utilization of the available space.

**Silhouette® Edition**

Clinac iX configuration that fits into an existing vault with a minimum room size of 16 feet (4.9 m) width by 19 feet (5.8 m) length. A variety of configuration and artistic panel options are available for creation of a customized radiation therapy treatment environment.

**Laser Alignment System**

- Wall and ceiling lasers
- Diode back pointer line laser

**CCTV Camera System**

This two-camera CCTV system is used for monitoring patient activity inside of the treatment room and patient activity from outside the room at the treatment console.

**Patient Intercom System**

The Patient Intercom System is used for audio communication with the patient in the treatment room from the treatment console area.

**Retractable Beam Stopper**

Transmission and leakage beyond the edge of the beam stopper, for field sizes up to 35 x 35 cm<sup>2</sup>, does not exceed 0.1%. With larger fields, leakage over a limited region beyond the diagonals can exceed this value to a maximum of approximately 0.3% for a 40 x 40 cm<sup>2</sup> field.

**Basic and Fine Beam Matching**

Refer to section 5.0.

**Factory Beam Data Set**

The optional Factory Beam Data Set is provided in hard copy and ASCII file formats. The data include physical wedge profiles, machine mechanical parameters, and representative beam data. Clinac iX accelerators are expected to match the data set per the Basic Beam Matching specifications in Section 5.0. The data set is not a substitute for the commissioning process but an aid to speed that process as well as data entry to treatment planning systems. The factory data are representative of the Clinac iX accelerator manufacturing standard, not the specific machine delivered.

**SmartConnect® Technology**

SmartConnect remote access technology connects the Clinac iX accelerator with Varian Customer Support for expert assistance and online remote analysis. Diagnostic and Morning Checkout Logs can be viewed remotely and transferred to Varian for report generation and trend analysis.

**RapidArc™ Radiotherapy Technology Treatment Delivery**

RapidArc generates IMRT quality dose distributions in a single optimized arc providing optimized treatment conformity. Dose per degree can be varied per degree of gantry motion (Refer to MLC Dynamic Control Specification, RAD 5610B).

*Specifications subject to change without notice.*





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